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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/516,437

11/30/2004

Scott Manzo

2843

2942

7590

05/21/2008

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60 Middletown Avenue  
North Haven, CT 06473

EXAMINER

HUANG, LIAN

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

05/21/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/516,437	<b>Applicant(s)</b> MANZO, SCOTT	
	<b>Examiner</b> LIAN HUANG	<b>Art Unit</b> 4148	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7 February 2005</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1- 6, 8-15, 17-19, and 22-25 are rejected under 35 U.S.C. 102(b) as being disclosed by **Yencho et al. (US 6,206,913)**.

**Regarding claim 1**, Yencho et al. disclose an apparatus for performing a surgical anastomosis, comprising:

a tubular sleeve (**134**) defining an axial lumen therethrough;

a positioning tube (**136**) defining an axial lumen therethrough, the positioning tube being configured and adapted to be slidably received within the axial lumen of the tubular sleeve (figure 28A);

an expansion assembly having a tubular body and an expandable tip operatively coupled to a distal end thereof, the expandable tip having a retracted position in which the expandable tip can pass through the axial lumen of the positioning tube and an expanded position in which the expandable tip can not pass through the axial lumen of the positioning tube (**148**, column 13, lines 14-16, where it is implied that **148** cannot pass through the axial lumen of the positioning tube, since it is deflated before sliding proximally for removal); and

an anchoring-assembly including:

a flange member (**122**) having a head portion and an expandable annular body integrally coupled to the head portion, the flange member defining a passage extending through the head portion and the annular body; and

a locking member (**111**) defining a lumen therethrough, the locking member being configured and adapted to radially deflect the expandable annular body upon insertion of the locking member within the passage of the annular body (where “within” is taken to mean “inside the limits of”).

**Regarding claim 2**, Yencho et al. disclose an apparatus as stated above wherein the expandable tip of the expansion assembly is a balloon (**148**).

**Regarding claim 3**, Yencho et al. disclose an apparatus as stated above wherein the annular body of the anchoring assembly comprises at least a pair of diametrically opposed longitudinal slots formed therein, wherein the annular body is expandable along the pair of longitudinal slots (**116**, please compare figure 28E and 28F).

**Regarding claim 4**, Yencho et al. disclose an apparatus as stated above wherein the annular body of the anchoring assembly includes a plurality of protuberances formed on an outer surface thereof (figure 16).

**Regarding claim 5**, Yencho et al. disclose an apparatus as stated above wherein the annular body of the anchoring has a first radius when not expanded radius and second radius, larger than the first radius, when expanded (figure 15, where **115** is expanded and **116** is not yet expanded, and the radius of **115** is greater than that of **116**).

**Regarding claim 6**, Yencho et al. disclose an apparatus as stated above wherein the head portion of the flange member (**122**) has a radius which is larger than the first radius of the annular body (figure 28F).

**Regarding claim 8**, Yencho et al. disclose an apparatus as stated above wherein the longitudinal slots extend through a proximal terminal end of the annular body and terminate at a distance spaced from the head portion (**116**, figure 28E).

**Regarding claim 9**, Yencho et al. disclose an apparatus as stated above wherein the head portion includes a plurality of protuberances formed on a proximal surface thereof (**122**, figure 29).

**Regarding claim 10**, Yencho et al. disclose an apparatus as stated above wherein the head portion includes a tapered distal surface (**147**).

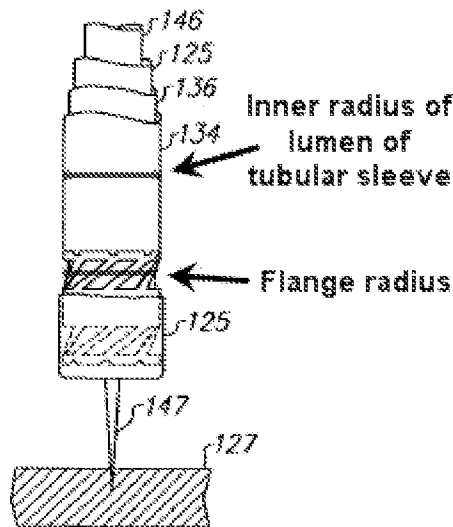
**Regarding claim 11**, Yencho et al. disclose an apparatus as stated above wherein the annular body of the anchoring assembly comprises a plurality of longitudinal slots formed therein (figure 24).

**Regarding claim 12**, Yencho et al. disclose an apparatus as stated above wherein the annular body of the anchoring assembly comprises at least one helical slot (where “helical” is taken to mean “having a shape approximating that of a helix”) extending through (figure 24, where “through” is taken to mean “up to and including”; please refer to the figure below) the terminal end of the annular body.

**Regarding claim 13**, Yencho et al. disclose an apparatus as stated above wherein a proximal end of the locking member (**111**) is configured and adapted to engage a distal end of the positioning tube (**136**, figure 24).

**Regarding claim 14**, Yencho et al. disclose an apparatus as stated above wherein the head portion of the flange member (**122**) has a radius which is larger than a radius of the lumen of the tubular sleeve (figure 28F).

**Regarding claim 15**, Yencho et al. disclose an apparatus as stated above wherein the head portion of the flange member (**122**) has a radius which is smaller than an inner radius of the lumen of the tubular sleeve (**134**; figure 24, please refer to the figure below).



**Regarding claim 17**, Yencho et al. disclose a method for performing a surgical anastomosis, comprising the steps of: providing an apparatus for performing an the surgical anastomosis, the apparatus comprising:

- a tubular sleeve (**134**) defining an axial lumen therethrough;
- a positioning tube (**136**) defining an axial lumen therethrough, the positioning tube being configured and adapted to be slidably received within the axial lumen of the tubular sleeve;

an expansion assembly having a tubular body and an expandable tip operatively coupled to a distal end thereof, the expandable tip having a retracted position in which the expandable tip can pass through the axial lumen of the positioning tube and an expanded position in which the expandable tip can not pass through the axial lumen of the positioning tube (**148**, column 13, lines 14-16, where it is implied that **148** cannot pass through the axial lumen of the positioning tube, since it is deflated before sliding proximally for removal); and

an anchoring assembly including:

a flange member (**122**) having a head portion and an expandable annular body integrally coupled to the head portion, the flange member defining a passage extending through the head portion and the annular body; and

a locking member (**111**) defining a lumen therethrough, the locking member being configured and adapted to radially deflect the expandable annular body upon insertion of the locking member within the passage of the annular body (where “within” is taken to mean “inside the limits of”);

passing the apparatus through a body lumen and through an opening in a body vessel such that the head portion of the flange member of the anchoring assembly is positioned within the body vessel (figure 28E);

advancing the expansion assembly through the positioning tube such that the expandable tip is within the body vessel;

expanding the expandable tip within the body vessel (figures 28C and 28D);

withdrawing the tubular body of the expansion assembly to press the head portion of the flange member of the anchoring assembly against the body vessel and to approximate the body vessel with the body lumen until the annular body of the flange member of the anchoring assembly is positioned within a distal end of the body lumen;

advancing the positioning tube through the tubular body to drive the locking member of the anchoring assembly into the annular body of the flange member and to deflect the annular body radially outward against the inner surface of the body lumen (figures 28A-H, column 11, lines 1-24).

**Regarding claim 18**, Yencho et al. disclose a method as stated above further comprising the step of retracting the expandable tip of the expansion assembly (column 13, lines 14-16).

**Regarding claim 19**, Yencho et al. disclose a method as stated above further comprising the step of withdrawing the tubular body (**134**), the positioning tube (**136**) and the expansion assembly (**148**) from the body lumen (column 13, lines 14-16, where **134** and **136** are part of **131** (column 11, lines 45-51)).

**Regarding claim 22**, Yencho et al. disclose an anchoring assembly for use in a surgical anastomosis procedure, comprising:

a flange member (**122**) having a head portion and an expandable annular body integrally coupled to the head portion, the flange member defining a passage extending through the head portion and the annular body; and

a locking member (**111**) defining a lumen therethrough, the locking member being configured and adapted to radially deflect the expandable annular body upon



insertion of the locking member within the passage of the annular body (where “within” is taken to mean “inside the limits of”).

**Regarding claim 23**, Yencho et al. disclose an anchoring assembly as stated above wherein the annular body of the anchoring comprises at least a pair of diametrically opposed longitudinal slots formed therein, wherein the annular body is expandable along the pair of longitudinal slots (**116**, please compare figure 28E and 28F).

**Regarding claim 24**, Yencho et al. disclose an anchoring assembly wherein the annular body of the anchoring assembly has a first radius when not expanded and a second radius, larger than the first radius, when expanded (figure 15, where **115** is expanded and **116** is not yet expanded, and the radius of **115** is greater than that of **116**).

**Regarding claim 25**, Yencho et al. disclose an anchoring assembly wherein the head portion of the flange member (**122**) has a radius which is larger than the first radius of the annular body (figure 28F).

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Yencho et al. (US 6,206,913)** in view of **Weadock (US 6,629,988 B2)**.

**Regarding claim 16**, Yencho et al. disclose an apparatus as stated above, but fails to teach it wherein the anchoring assembly is made from a bio-absorbable material.

However, Wendock teaches an anchoring assembly made from bioabsorbable material (**12**).

It would be obvious to one of ordinary skill in the art at the time of the invention to have the anchoring assembly be made from bioabsorbable material as taught by Wendock, since Wendock states that making the assembly with bioabsorbable material allows the assembly to be resorbed as the anastomosis heals (column 2, lines 43-60).

5. Claims 7, 26, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Yencho et al. (US 6,206,913)** in view of **Evard et al. (US 6,206,913)**.

**Regarding claim 7 and 26**, Yencho et al. disclose an apparatus and assembly as stated above wherein the locking member (**111**) comprises a cylindrical body having a distal end portion, wherein the cylindrical body has a radius which is larger than the first radius of the annular body, but fails to teach it wherein the distal end portion of the cylindrical body tapers down to a radius which is smaller than the first radius of the annular body.

However, Evard et al. teach a cylindrical member between two flanges wherein the cylindrical body tapers (figures 1 and 2).

It would be obvious to one of ordinary skill in the art at the time of the invention to have the locking member taper as taught by Evard et al., since Evard et al. state that such a modification would maintain a minimum passageway diameter between the openings of the connected anatomical structures (column 3, lines 5-8).

**Regarding claim 27**, Yencho et al. disclose an anchoring assembly wherein the longitudinal slots extend the annular body and terminate at a distance spaced from the head portion (**116**, figure 24).

6. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Yencho et al. (US 6,206,913)** in view of **Edelstein (US 5,591,179)**.

**Regarding claim 20**, Yencho et al. disclose a method as stated above, but fails to teach it wherein the surgical anastomosis is a radical prostatectomy.

However, Edelstein teaches using the technique of anastomosis in radical prostatectomy (column 4, line 53).

It would be obvious to one of ordinary skill in the art at the time of the invention to apply the technique of anastomosis to radical prostatectomy as taught by Edelstein to expand the uses of Yencho et al. for the predictable result of enabling an additional method of performing radical prostatectomy.

**Regarding claim 21**, Yencho et al. disclose a method as stated above, but fails to teach it wherein the radical prostatectomy includes the steps of removing the prostate gland from between the urethra and the bladder to define a urethral stump and a bladder neck.

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However, Edelstein teaches using the technique of removing the prostate gland to define a urethral stump and bladder neck (column 4, lines 51-62).

It would be obvious to one of ordinary skill in the art at the time of the invention to apply the technique of removing the prostate gland to radical prostatectomy as taught by Edelstein to expand the uses of Yencho et al. for the predictable result of enabling an additional method of performing radical prostatectomy.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following references are cited for disclosing related limitations of the applicant's claimed and disclosed invention:

US 6280460 B1	Bolduc; Lee R. et al.
US 20060200177 A1	Manzo; Scott E.
US 20050228411 A1	Manzo, Scott
US 20050171564 A1	Manzo, Scott E
US 20050171563 A1	Heinrich, Russell et al.
US 20050165432 A1	Heinrich, Russell
US 20050165378 A1	Heinrich, Russell et al.
US 6176864 B1	Chapman; Troy
US 5797934 A	Rygaard; Jorgen A.
US 5540701 A	Sharkey; Hugh R. et al.
US 5674231 A	Green; David T. et al.

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US 6695859 B1	Golden; Steve et al.
US 3254650 A	COLLITO MICHAEL B
US 5951576 A	Wakabayashi; Akio
US 5545171 A	Sharkey; Hugh R. et al.
US 4911164 A	Roth; Robert A.
US 20020082614 A1	Logan, John et al.
US 6428555 B1	Koster, Jr.; J. Kenneth
US 6409739 B1	Nobles; Anthony A. et al.
US 6346074 B1	Roth; Alex T.
US 6726694 B2	Blatter; Duane D. et al.
US 7160311 B2	Blatter; Duane D. et al.
US 6569173 B1	Blatter; Duane D. et al.
US 6371965 B2	Gifford, III; Hanson S. et al.
US 7022127 B2	Suyker; Wilhelmus Joseph Leonardus et al.
US 7018387 B2	Suyker; Wilhelmus Joseph Leonardus et al.
US 6676678 B2	Gifford, III; Hanson S. et al.
US 7331613 B2	Schulte; Gregory T.
US 7320692 B1	Bender; Theodore M. et al.
US 7314480 B2	Eidenschink; Tracee et al.
US 7303569 B2	Yencho; Stephen et al.
US 7285125 B2	Viola; Frank J.
US 7267680 B2	Wright; David Walter

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US 7241300 B2	Sharkawy; A. Adam et al.
US 7232449 B2	Sharkawy; A. Adam et al.
US 7182771 B1	Houser; Russell A. et al.
US 7131959 B2	Blatter; Duane D. et al.
US 7128749 B1	Vargas; Jaime et al.
US 7115136 B2	Park; Adrian Edward et al.
US 7104949 B2	Anderson; Kimberly A. et al.
US 7094248 B2	Bachinski; Thomas J et al.
US 7060084 B1	Loshakove; Amir et al.
US 7001398 B2	Carley; Michael T. et al.
US 6960219 B2	Grudem; Jerry et al.
US 6939361 B1	Kleshinski; Stephen J.
US 6920882 B2	Berg; Todd Allen et al.
US 6884250 B2	Monassevitch; Leonid et al.
US 6866674 B2	Galdonik; Jason A. et al.
US 6830584 B1	Seguin; Jacques
US 6802847 B1	Carson; Dean F. et al.
US 6800081 B2	Parodi; Juan C
US 6736825 B2	Blatter; Duane D. et al.
US 6699256 B1	Logan; John et al.
US 6695867 B2	Ginn; Richard S. et al.
US 6682540 B1	Sancoff; Gregory E. et al.

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US 6666873 B1	Cassell; Jack L.
US 6632229 B1	Yamanouchi; Eigo
US 6623510 B2	Carley; Michael T. et al.
US 6623494 B1	Blatter; Duane D.
US 6620176 B1	Peterson; Alex Alden et al.
US 6602263 B1	Swanson; William J. et al.
US 6558429 B2	Taylor; Thomas V.
US 6533812 B2	Swanson; William J. et al.
US 6508252 B1	Berg; Todd Allen et al.
US 6488692 B1	Spence; Paul A. et al.
US 20050033371 A1	Sommer, John L. et al.
US 20040127854 A1	Leinsing, Karl R. et al.
US 20040111056 A1	Weststrate, Patrice A. et al.
US 6796586 B2	Werth; Albert A.
US 1390564 A	KNORR FREDERICK J
US 4334551 A	Pfister; Robert D.
US 7112212 B2	Raza; Syed Tasnim
US 7351247 B2	Kupiecki; David et al.
US 7041110 B2	Yencho; Stephen A. et al.
US 7004949 B2	Yencho; Stephen A. et al.
US 6461320 B1	Yencho; Stephen A. et al.
US 6171321 B1	Gifford, III; Hanson S. et al.

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US 6152937 A      Peterson; Alex Alden et al.

US 4366819 A      Kaster; Robert L.

US 6629988 B2      Weadock; Kevin S.

US 7309341 B2      Ortiz; Mark S. et al.

US 6984238 B2      Gifford, III; Hanson S. et al.

US 6635066 B2      Tanner; Howard et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LIAN HUANG whose telephone number is (571)270-3987. The examiner can normally be reached on 7:30 AM-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrell McKinnon can be reached on 571-272-4797. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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Supervisory Patent Examiner, Art Unit 4148